REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and the reasons that follow.

Claims 1, 2, 4-25 and 43 are pending in this application, with claim 3 being withdrawn. Claim 1 is amended to correct for dependency. Claims 1 and 17 are amended. Support for the amendment may be found throughout the specification as originally filed. No new matter is added by way of amendment. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented with an appropriate status identifier.

I. Claim Rejections Under 35 U.S.C. § 112.

Claim 6 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for "the socket" failing to have antecedent basis in claim 1. In view of the amendment to claim 6, Applicant submits that the rejection is now moot and requests withdrawal of the rejection.

II. Claim Rejections Under 35 U.S.C. § 101.

Claims 1, 2, and 4-20 stand rejected under 35 U.S.C. § 101, as being directed to non-statutory subject matter. The Examiner alleges that Claims 1 and 17 recite parts of the human body in combination with the device. In view of the above amendment to Claims 1 and 17, Applicant respectfully traverses this rejection, and requests withdrawal of the rejection.

III. Claim Rejections Under 35 U.S.C. § 102.

Claims 1, 2, 4-12, 16-25, and 43 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,241,730 issued to Alby. Applicant respectfully traverses this rejection.

As explained in MPEP 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Applicant submits that Alby fails to teach at least the element of "a disc prosthesis or

a disc nucleus replacement adapted to be disposed between two adjacent vertebrae in the spinal column." As described in the specification, the disc prosthesis or a disc nucleus replacement is used "to retain or simulate at least some of the physiological intervertebral mobility of the spine." Paragraph 8.

Alby teaches an intervertebral link device capable of axial and angular displacement. Title. Overall, the device of Alby is direct to arthrodesis or bone fusion, as the intervertebral stabilization device is adapted to allow micromovements so as to ensure bone fusion. Col. 1, lines 26-29 and col. 2, lines 20-22. There simply is no teaching in Alby, either expressly or inherently, of a disc prosthesis or disc nucleus replacement, as recited in Claim 1. In fact, because Alby is directed to spinal fusions, even a suggestion to use the device of Alby with such replacements is unfounded, as the replacements are intended to preserve intervertebral mobility of the spine.

Without a teaching of each and every element of the claims as presented, Alby cannot be found to support an anticipation rejection. As such, Applicant respectfully requests withdrawal of the rejection under §102.

IV. Claim Rejectio ns Under 35 U.S.C. § 103.

Alby and Crozet

Claims 13 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Alby in view of U.S. Patent No. 6,217,578, issued to Crozet *et al.* Applicant respectfully traverses this rejection.

Applicant submits that, as noted above, Alby fails to provide for each and every element of Claim 1, from which claims 13 and 14 depend, and further that Crozet fails to fill the voids of Alby. Crozet is directed to a vertebral osteosynthesis device that can be used to brace a spine ... or to strengthen or brace a deviated spine. Col. 1, lines 5-11. To accomplish this, the device provided is a cross connector device having a low profile that allows for substantial degree of freedom between the hooks of the device. Col. 2, lines 15-18. The cross connector device is for

coupling dual rods of an orthopaedic apparatus together to provide enhanced stability thereto. Col. 7, lines 29-32. There simply is no teaching of a device with at least the element of "a disc prosthesis or a disc nucleus replacement."

Because Crozet fails to correct the deficiency of Alby with respect to Claim 1, from which claims 13 and 14 depend, Applicant request that the Examiner withdraw the rejection based upon Alby and Crozet and allow the application to move forward to issuance.

Alby and Karpman

Claim 15 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Alby in view of U.S. Patent No. 6,214,012, issued to Karpman *et al.* Applicant respectfully traverses this rejection.

As noted above, Alby fails to teach each and every element of the claims as pending, and Applicant submits that Karpman fails to fill the void. Karpman is directed to a bone screw which is configured for delivery of an injectable material into a bone. Col. 1, lines 6-9. Applicant submits that while a bone screw is taught for the delivery of a material to a diseased site, there is no teaching or suggestion in Karpman of at least the element of "a disc prosthesis or a disc nucleus replacement." As such, Applicant respectfully requests withdrawal of the noted rejection.

However, Applicant further addresses the rejection in view of the McLeer reference below. The Examiner relies upon Karpman for teaching that bone cement is used in enhancing fixation of screws, and then further upon U.S. 2006/0079895, applied for by McLeer, as showing that bone cement is a tissue-growth resistant material. (Note that McLeer is not a proper reference against the instant application as the earliest priority date is September 30, 2004, and the instant application claims priority to November 25, 2003.) Applicant directs the Examiner's attention to the fact that the bone-growth inhibiting material of Claim 15 is "disposed around the pivoting joint." The bone-growth inhibiting material is used to preserve motion of the pivoting

joint and not allow the pivoting joint to fuse due to tissue growth. Because use of a cement would result in fusion of the pivoting joint, reliance upon Karpman and McLeer is misplaced.

While Karpman does teach the use of bone cement for the fixation of screws to bone, the teaching of McLeer vitiates the suggested use of a cement as a bone growth inhibiting material in the presently claimed invention. The full paragraph to which the Examiner cites in McLeer is paragraph 46, recited here:

> In various embodiments, bone cement and/or an adhesive can be applied to the various mechanical fixation regions to enhance the mechanical attachment of the fixation element(s) into the vertebra. Where ***some*** bone cement(s) and/or adhesive(s) ***tend to inhibit*** bone and soft tissue in-growth, *the use of these materials would desirably be limited to the mechanical fixation regions and the migration of such substances (or their biological effects) into the bio-fixation regions would be inhibited and/or prevented*. Accordingly, in various embodiments, one or more gaps may be formed or left between the mechanical and bio-fixation regions, or one or more cement restrictors or flow restrictors can be placed between these various regions. In addition or alternatively, bioactive/bio-degradable sealants can be used to inhibit cement or adhesive flow into the bio-fixation region(s). In the case of a sealant (including materials that can be used as sealants such as Poly Lactic Acid, Poly Glycolic Acid or calcium sulfate, etc.), the sealant or other like material could comprise a bio-active, bio-degradable or hydrolytic-degradable material which desirably prevents bio-inhibitive materials from migrating into the bio-fixation region(s), but which eventually allows bio-in growth to occur there-through (for example, the sealant could degrade within the human body, thereby allowing subsequent infusion of biogrowth therethrough). In alternative embodiments, resorbable/remodelable bioactive cements (such as calcium phosphate or Norian.RTM. Skeletal Repair Cement) could be incorporated around and/or in the implanted device, or manufactured as part of the cement or other securement component of the implanted device.

Emphasis added. In this quoted section of McLeer, it is evident that while *some* bone cements may be bone-growth inhibiting, their use in bio-fixation regions is undesirable. If Applicant were to use a bone cement, as suggested by the Examiner, there would be no pivoting joint and that entire aspect of the claim would be negated. As such, the Examiner's reliance upon Karpman and McLeer is misplaced, as a bone cement would render the instantly claimed invention unsuitable for its intended purposed. Applicant respectfully requests withdrawal of this rejection.

Applicant submits that the present application is now in condition for allowance and respectfully requests withdrawal of the remaining rejections.

V. Rejoinder

In view of the above remarks, Applicant respectfully requests rejoinder of withdrawn Claim 3. In the Office Action, mailed May 4, 2007, the Examiner had acknowledged that once a generic claim, in this case, Claim 1, was found allowable, non-elected species would be subject to rejoinder. Page 3. In the same Office Action, the Examiner alleged that because there is no art of record that a plate and a rod are obvious variants, they are distinct species. Page 2. However, in view the primary Alby reference cited by the Examiner in the instant Office Action, this is no longer a true statement, as the interchangeability of plates and rods is now of record. At Col. 1, lines 50-55, Alby states;

> Nevertheless, it appears that an intervertebral stabilization device, *whether of the plate type or of the rod type*, once implemented, constitutes a system that is rigid, thereby applying mechanical stresses to the intervertebral joints adjacent to the joint being stabilized.

Thus, there is evidence in the art cited to by the Examiner that one of skill in the art would consider a rod and a plate to be interchangeable species in spinal devices.

As Claim 1 distinguishes over the cited art for the reasons presented above, Applicant respectfully submits that Claim 3 may be rejoined with the other pending claims, as dependent upon an allowable generic claim.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is earnestly solicited. The Examiner is requested to contact the undersigned by telephone if a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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By _____

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